

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	09/925,063	Group Art Unit:	1615
Applicant(s):	Barnes, S. and Ding, J.	Examiner:	JOYNES, ROBERT M.
Filing Date:	August 8, 2001	Docket No.	70373-010100
Title:	CALENDERED HYDROCOLLOIDAL DRESSING		
		Customer No.	33717

DECLARATION OF SCOTT BARNES

I, Scott Barnes, hereby declare as follows:

1. I am the Vice President , R&D (Calendered and Extruded Products) for Scapa North America. I have been employed by Scapa for approximately 12 years and have held this position for the last year. Upon joining the company in 1992, I held the position of Product Development Manager (5 years) followed by Technical Manager (4 years) then Technical Director (2 years). My responsibilities have included all aspects of product development, process development, quality assurance and engineering. In my current role, I oversee all R&D activities related to calendering and extruding technologies, both product and process development. I am a member of our North American Board of Directors and thus participate in setting policy and strategy for our North American Operations. My office is located at 609 Barnet Boulevard, R.R.#1 Station Main, Renfrew, Ontario K7V 3Z4, Canada.

2. My educational background is Chemical Engineering with a B.Sc. degree granted in 1986. Prior to joining Scapa in 1992, I worked primarily as a Development Engineer for three companies, all involved extrusion and laminating technologies.

3. Scapa North America is the exclusive assignee under the above-identified application.

4. Particular aspects of the present invention are directed to calendered hydrocolloid dressings for wound care and a one step method of forming and calendering an adhesive

layer/film, comprising a particular composition, onto a formed backing layer/film in order to provide a hydrocolloidal dressing.

5. Prior art methods for hydrocolloidal dressing are typically narrow web processes utilizing pre-made filmic substrates. The hydrocolloid mass can be formed into a layer on release paper one step followed by lamination to a pre-made film in another. Alternatively, hydrocolloid mass can be extruded directly on to a pre-made film that serves as the backing layer. In both cases, narrow webs are employed and pre-made films are utilized resulting in high manufacturing costs. The ability to run wider widths and produce the dressing in a single manufacturing steps brings about significant cost savings.

6. The present invention is that the present application claims a single step of layer formation and lamination onto a backing layer resulting in a clear economic advantage for producing calendered hydrocolloid dressings, as opposed to prior art methods of forming the adhesive layer separately, for example as a pre-made film and typically at another manufacturing location. Such rolls have to be handled, transported and loaded onto additional machinery at another location where the adhesive film/layer is then laminated to onto a backing layer/film as an independent and separate step in the manufacturing process. The claimed methods result in improved manufacturing efficiency and hence provide an economic advantage over prior art methods.

7. I have review the Office Action dated March 23, 2004 and the references cited and relied upon in that Office Action, including specifically U.S. Patents Nos. 5,059,189 to *Cilento, et al.*, 4,994,278 to *Sablotsky, et al.* and 5,372,819 to *Godbey, et al.*.

8. After analyzing the disclosures of all three of these cited references, I assert that there is no teaching or suggestion found in any of these references, alone or in combination, that meets the particulars of the independent method claims that are currently pending. In fact, there are no relevant method steps or manufacturing methods disclosed in the various cited references that relate to pending method claims steps. Particularly, there is nothing in this patent that even mentions a one-step manufacturing step where an adhesive composition is calendered between a center roll and a lower roll (for example, of a vertical 3 roll calendering apparatus See FIG. 3 of the application) so that a polymeric pressure-sensitive adhesive composition is applied and

calendered directly onto the backing film layer such that formation of an adhesive layer of said polymeric pressure-sensitive adhesive composition and lamination of said adhesive layer to said backing film layer is achieved in a single manufacturing step. There is simply nothing in the *Cilento et al.* reference that even remotely relates to such a manufacturing step, nor is there any recognition in this or in the other cited references of the improved efficiencies/advantages that our claimed methods provide, as disclosed above. In fact, the only manufacturing methods disclosed in the three references are found in the *Cilento et al.* patent and these are standard techniques in the art.

9. In particular, the *Cilento et al.* patent simply and only teaches that an "... adhesive mass is layered onto a sheet of silicone coated release paper, flattened to the desired thickness by either calendering or extruding, and a flexible backing and a flexible backing member is laminated to the other surface of the adhesive layer" (please see Col 7, lines 23-36). This teaching is clearly unlike the present claims. *Cilento et al.* teaches a three step process that includes 1) layering and adhesive mass onto a sheet of silicon release paper, then 2) flattening or extruding the adhesive layer that is disposed onto this sheet of silicon coated release paper, then 3) to this sheet of silicon coated release paper with adhesive, laminating, in a separate step, a flexible backing. As stated above, these steps are simply standard prior art techniques and have nothing to do with, nor make obvious our novel manufacturing process by which an adhesive layer is disposed upon, calendered and laminated to a backing film/layer in one step.

10. The disclosure of *Sablotsky et al.*, in combination with *Cilento et al.*, also fails to teach, suggest, disclose any information that remedies the shortcomings of *Cilento et al.*, that is, mention or describe the manufacturing method steps that are enumerated in the method claims pending in the present patent application. *Sablotsky et al* simply discusses various properties (such as vapor transmission rates) and components that provide a backing for transdermal compositions. There is no mention of our novel manufacturing steps, and in fact the only mention regarding manufacturing relates to co-extrusion and lamination to form a backing, which are well known and standard in the industry (Col. 8, lines 33-37) and have nothing to do with our manufacturing method in which one step is utilized to dispose, calender and laminate an adhesive layer upon a backing film/layer in one step.

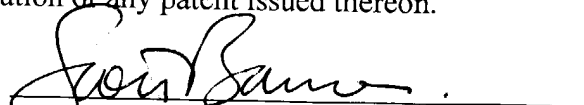
11. Similarly, the disclosure of *Godbey et al.* when taken in further combination with *Cilento et al.* and *Sablotsky et al.*, also fails to teach or disclose any information which leads one to the novel processes that are currently claimed in the present patent application. Like *Sablotsky et al.* and *Cilento et al.*, *Godbey et al.* is directed to disclosing various proportions of components that provide polymer blends to which various active ingredients may be added, and not to disclosing any details of manufacturing steps, let alone the novel and more efficient method steps that we have invented and are presently claiming.

12. I note that the Examiner in this case has consistently (in the Office Action of March 23, 2004 as well as in the previous office actions in the case) based his rejections of our method claims by referring to the compositions disclosed in the various references.

13. In summary, it is my professional opinion that the references cited by the Examiner alone or in any combination, do not teach, disclose or even suggest the manufacturing methods that we present and are pending in this patent application.

I further declare that all statements made herein of my knowledge, are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: August 19, 2004



Scott Barnes